UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This document relates to all actions.**	MDL No. 2875 Civil No. 19-02875 (RBK/SAK) Hon. Robert B. Kugler, U.S. District Court Judge

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR CLASS CERTIFICATION OF THIRD-PARTY PAYOR CLAIMS

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INTRODUCTION

Third-party payors ("TPPs") do not consume prescription drugs and are not at risk of harm from any impurities that those drugs may contain. Rather, they pay for a portion (or all) of consumer prescription costs under prescription drug insurance plans. Nevertheless, TPP plaintiffs MSP Recovery Claims, Series, LLC ("MSPRC") and Maine Automobile Dealers Association, Inc. Insurance Trust ("MADA") (collectively, "TPP Plaintiffs") contend that all TPPs that paid for valsartan, alone, or in combination with other anti-hypertensive drugs (collectively, "valsartan-containing drugs" or "VCDs") manufactured by Defendants from 2012 to 2019 were injured because the VCDs were rendered worthless by virtue of the alleged presence of N-Nitrosodimethylamine ("NDMA") or N-Nitrosodiethylamine ("NDEA") in some of them. These claims, which all sound in economic loss, are even less suited for class treatment than the claims advanced by the individual consumers. The Court should deny certification for several reasons.

First, the TPP Plaintiffs' claims fail the typicality requirement of Rule 23(a) and the predominance requirement of Rule 23(b)(3). The TPP Plaintiffs' proposed subclasses do not adequately address the numerous variations in governing law, and their proposed class is rife with individualized factual issues. As a result, determining (1) whether Defendants' actions caused harm to the TPP Plaintiffs; (2) the existence of injury and amount of any damages; and (3) whether the TPP Plaintiffs relied on Defendants' alleged misrepresentations would require TPP-by-TPP, if not member-by-member, assessments.

Second, any class trial would be unmanageable in the extreme. The TPP Plaintiffs apparently propose to try the 21 TPP subclasses together with the 93 individual consumer subclasses in a ***114-subclass***, three-phase trial, partially to a jury and partially to the bench. No court or jury could possibly keep each subclass straight in a trial of such dizzying complexity. Nor could the Court meaningfully instruct a jury on so many different legal standards. And to the extent

the TPP Plaintiffs propose an alternative TPP-specific trial, they have offered no plan to explain how it would proceed. In addition, there is an obviously superior option for adjudicating the TPP claims: individual trials. Each TPP has likely paid for hundreds, if not thousands or even millions of prescriptions; thus, these claims have sufficient potential value to be tried individually.

Third, neither MSPRC nor MADA is a typical or adequate class representative. As a threshold matter, the named TPP Plaintiffs did not suffer a concrete injury and therefore lack standing. Moreover, MSPRC will be subject to unique defenses because: (1) the claims it asserts were assigned to it by other TPPs, and the validity of the assignments is subject to dispute; and (2) its serial litigation against insurers in other cases gives rise to a clear conflict of interest. For its part, MADA appears to have no real understanding of its claims, as evidenced by the fact that its corporate representative repeatedly failed to answer basic questions at her deposition.

Finally, membership in the class and subclasses proposed by the TPP Plaintiffs cannot be determined in an administratively feasible manner. The pharmaceutical distribution and payment chain is much more complex than the TPP Plaintiffs acknowledge, making the TPP Plaintiffs' ill-conceived method of identifying the proposed class members administratively infeasible. And even if the TPP Plaintiffs could feasibly identify the members of their proposed class, the class definition itself is impermissibly vague.

FACTUAL BACKGROUND

A. Proposed TPP Class Representatives MADA And MSPRC

MADA is an insurance trust administered by The Maine Automobile Dealers Association, Inc., a trade association of car dealerships. *See* Ex. 44, Dep. of Patricia Cobb ("Cobb Dep."), Oct. 21, 2021, Ex. 3, at MADA000468; Ex. 31, Dep. of Thomas Brown ("Brown Dep.") 32:13-33:11, May 28, 2021. Most of its member dealerships provide their employees with healthcare coverage through one of MADA's plans. Brown Dep. 33:12-25; *see also* Third-Party Payors' Br. in Supp.

of Mot. to Certify Class (ECF 1749) ("TPP Br.") at 2. MADA self-funds medical and prescription drug benefits with contributions from its members, Brown Dep. 80:12-22, 124:14-18, but it contracts with an outside organization to administer them, *see, e.g.*, *id*. 96:20-97:9.

MSPRC is not a TPP and has never been a plan sponsor. Ex. 30, Dep. of Jorge A. Lopez ("Lopez Dep.") 24:6-25:5, Apr. 29, 2021. Rather, it is a holding company with subsidiaries that have been assigned Medicare-related claims from actual TPPs: Summacare, Inc. ("Summacare"), EmblemHealth, Inc. ("Emblem"), and ConnectiCare, Inc. ("CTCare"). *See* ECF 1708 ¶¶ 60-67. MSPRC's affiliate entity, MSP Recovery, LLC, stores, reviews and analyzes claims data, Lopez Dep. 132:6-24, and its affiliated law firm sues over them, *id*. 134:6-135:8.

B. TPPs And Other Participants In The Pharmaceutical Supply Chain.

TPPs are just one part of the intricate web of manufacturers, wholesalers, pharmacies, third-party administrators ("TPAs"), insurance providers, Administrative Services Only providers ("ASOs"), federal and state governments, and pharmacy benefit managers ("PBMs") that make up the pharmaceutical supply chain and benefits flow, all of which may (or may not) be involved in any given prescription payment. The TPP Plaintiffs describe a "TPP" as any party that was ultimately responsible "in whole or in part" for paying the cost of a VCD prescription after the insured's co-pay or co-insurance contribution. *See* TPP Br. at 2. TPPs come in various forms, including (1) self-insured employers that provide prescription coverage to their employees; (2) insurance companies that provide "fully insured" plans to clients; (3) companies that offer Medicare Part D plans (either standalone or as part of a Medicare Advantage plan); and (4) companies that offer state Medicaid Managed Care ("MMC") plans. *See* Ex. 192, Expert Report of Timothy E. Kosty ("Kosty Rep.") ¶¶ 42-56, Jan. 12, 2022.

MADA is an example of the first type of TPP, a trade association that self-funds its prescription benefits plan for its members' employees. *See* TPP Br. Ex. 1, Expert Declaration of

Laura R. Craft ("Craft Decl.") ¶¶ 37, 67, Nov. 10, 2021. MSPRC's assignors Emblem, Summacare and CTCare are examples of the second, third and fourth types of TPPs. All three provide "fully insured" plans to some of their clients, as well as Medicare Advantage plans directly to consumers. *See* Kosty Rep. ¶¶ 47, 50. Emblem also offers a Medicaid Managed Care plan to low-income persons. *See* Ex. 29, Dep. of Margaret Finn 32:4-33:1, July 30, 2021. MSPRC's assignors also operate as ASO providers to certain self-funded prescription drug plan sponsors. Kosty Rep. ¶ 47. Depending on the assignors' role with respect to a particular client, they may or may not qualify under Plaintiffs' definition of TPPs. Providers of fully insured plans are ultimately at risk for prescription costs and therefore are TPPs under Plaintiffs' definition; providers of Medicare Advantage plans and Medicaid Managed Care plans are heavily subsidized by the federal government[1] and therefore subject to class exclusions or damages offsets; and providers of ASO services are not at any risk and therefore are ***not*** TPPs under Plaintiffs' definition. Kosty Rep. ¶ 47.

TPPs generally do not contract directly with pharmacies to pay for prescriptions. Rather, TPPs contract with one or more intermediaries to administer their prescription claims. *See* Kosty Rep. ¶ 39 Fig. 1, ¶ 98 Fig. 3. At least a PBM, and possibly other entities, were involved in every insured pharmaceutical transaction at issue in this case. *Id*. The PBM pays the pharmacy for the drug directly and then seeks repayment from its client. *See* Kosty Rep. ¶¶ 39-40, 102. In some cases, the client is a TPP, *id*. ¶ 39 Fig. 1, and the PBM bills the TPP directly. In other cases, a TPP

[1] Medicare Part D, Medicare Advantage and state MMC plans receive, directly from the state or federal government, an upfront contribution to cover the majority of their anticipated prescription drug costs. The federal government prospectively pays them a sum intended to cover 74.5% of their anticipated drug costs (with the remainder of each TPP's expenses covered by the premiums paid by the TPP's members). Kosty Rep. ¶ 84. These TPPs may also receive additional payments from the government to cover drug costs if their realized drug costs exceed their initial estimate or if members reach the "catastrophic" phase of Medicare Part D coverage. *Id*. Similarly, TPPs providing MMC plans, which cover two-thirds of Medicaid beneficiaries nationwide, receive an upfront monthly payment for the expected costs of the medications they cover. *Id*. ¶ 54.

will contract with a TPA or ASO provider. *Id*. ¶ 98 Fig. 3; Craft Decl. ¶ 68. About half of self-funded employers who provide health coverage to employees contract with a TPA instead of directly with a PBM. Kosty Rep. ¶ 60. In those cases, the TPA or ASO pays the PBM, *see* Kosty Rep. ¶ 102, and then bills its client (often, but not always, the TPP), Ex. 49, Dep. of Laura R. Craft ("Craft Dep.") 147:19-149:2, Feb. 18, 2022.

C. The TPP Plaintiffs' Proposed Class And Subclasses

The TPP Plaintiffs have proposed a TPP class consisting of:

> all Third-Party Payors that, from at least January 1, 2012 through the date of final recall as of November 10, 2021, paid any amount of money in the United States for a [VCD] (intended for personal or household use) that was manufactured, distributed, or sold by any Active Pharmaceutical Ingredient, Finished Dose or Wholesaler Defendant.

ECF 1747-2 at 1. The TPP Plaintiffs further propose dividing the TPP class into 21 subclasses, grouped by theory of liability and applicable state law. *See, e.g., id*. at 3. The TPP Plaintiffs seek to certify four theories of liability against the Manufacturer Defendants: breach of express warranty, breach of implied warranty, common law fraud, and violation of state consumer protection statutes. They also seek certification for just one theory, unjust enrichment, against wholesalers, who have filed a separate opposition. They bring no claims against pharmacies.

D. TPPs' Net Costs For VCDs Vary From One Transaction To The Next Due To Pre- And Post-Sale Adjustments.

When an insured consumer fills a prescription at a pharmacy, the pharmacy generates a claim against that consumer's prescription drug coverage, and usually requires some amount of co-pay or co-insurance. Kosty Rep. ¶ 40(c) n.40. The TPP Plaintiffs deem this event to be the "point of sale," and they premise their damages model entirely on the value of this transaction. *See* TPP Br. Ex. 2, Expert Declaration of Rena Conti, Ph.D. ("Conti Decl.") ¶ 56 n.52, Nov. 10, 2021. In reality, however, pre- and post-point-of-sale transactions greatly affected the net outlay that

TPPs actually paid for VCDs. TPPs providing Medicare Part D/Advantage and/or MMC plans receive heavy government subsidies prior to the point of sale, covering most of the money they pay for VCDs. And if a Part D TPP's costs exceed its initial bid, the government pays the TPP additional money post-sale pursuant to "risk corridors." *See* Kosty Rep. ¶ 84(b). In addition, for Part D plans, PBMs charge pharmacies direct and indirect remuneration fees, which can be credited back to TPPs after the point of sale. *See* Kosty Rep. ¶ 40(d)(iv). These offsets are not unique to Medicare plans. For example, the federal government pays a Retiree Drug Subsidy ("RDS") to employers and unions that offer non-Medicare drug coverage to retirement-age persons. *Id.* ¶ 84(e). Additionally, some TPPs negotiate performance guarantees with their TPA, ASO or PBM, by which the TPP receives money back if the TPA/PBM fails to obtain a medication at or below an agreed-upon price. *See, e.g.*, Ex. 40, Cobb Dep., Ex. 2, at MADA000286-93; *see also* Kosty Rep. ¶¶ 59 & n.88, 61 n.95. Moreover, claims can be reversed after the point of sale, for instance because the TPP determines that the medication was not covered or the consumer's coverage has lapsed. *See* Ex. 32, Cobb Dep. 77:18-78:4, 102:17-103:8. Lastly, a TPP may receive a refund for medications as a result of a recall, making it whole for any prior payment.

E. TPPs Pay For Prescription Drugs Based On Drug Formularies.

The extent to which a TPP will cover the cost of a generic medication, such as a VCD, is governed by its formulary, a continually updated list of medications approved for reimbursement. Approved medications are sorted into tiers, generally structured to encourage members to use the most cost-effective generic drugs available. Kosty Rep. ¶ 76-77. Pharmacy and Therapeutics Committees ("P&T Committees") evaluate medications for inclusion on formularies. *See id.* ¶ 65. Most P&T Committees are associated with PBMs or health insurance organizations, but some TPPs have their own P&T Committees. *See* TPP Br. Ex. 3, Expert Report of Kali Panagos ("Panagos Rep.") ¶ 22 & n.2, Nov. 9, 2021. A drug's formulary placement helps indicate what a

TPP would have paid for an alternative medication if the VCDs at issue were not available for purchase. [redacted]. Kosty Rep. ¶ 172 & n.321 (citing MSP-SUMMACARE-000162-274). The benefit design of a prescription drug plan—including co-pays, co-insurances, generic purchase requirements and maximum out-of-pocket limits—can affect a TPP's share of any payment for an alternative, non-VCD drug. *See* Kosty Rep. ¶¶ 76-79, 81-82.

F. Consumers And Regulators Valued The At-Issue VCDs.

At the time of the valsartan recall, the FDA confirmed the health benefits of VCDs by recommending that consumers continue to use their medicine until they could obtain a replacement product. Kosty Rep. ¶¶ 10, 166. Some individual consumers, including many of the named plaintiffs for the proposed Economic Loss Class, heeded this recommendation. *Id.* ¶ 165.

LEGAL STANDARD

Defendants adopt and incorporate the discussion of the Rule 23 legal standards from the Argument section of Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion for Class Certification of Consumer Economic Loss Claims (the "Consumer Opposition brief" or "Consumer Opp. Br."). The TPP Plaintiffs' class proposal does not satisfy these standards.

ARGUMENT

I. PLAINTIFFS CANNOT SATISFY RULE 23(b)(3)'S PREDOMINANCE REQUIREMENT.

A. Common Legal Questions Do Not Predominate Over Individualized Ones.

The TPP Plaintiffs' claims are governed by "the law[s] of [their] home state[s]," *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 2875, 2021 WL 307486, at *8

(D.N.J. Jan. 29, 2021),[2] which vary substantially and materially. Plaintiffs purport to address these legal variations with a series of subclasses, but, as explained in greater detail in Defendants' Consumer Opposition brief and its appendices (incorporated in full herein), these groupings are based on superficial legal analyses that ignore profound and potentially outcome-determinative legal distinctions within the proposed subclasses.

Of particular note, the TPP Plaintiffs seek certification of four proposed "violation of state consumer protection laws subclasses," ECF 1747-2 at 3, that do not sufficiently account for material variations among the various states' laws with respect to whether commercial entities can bring consumer protection claims. For example, subclass A includes both Connecticut and Hawaii. Under Connecticut's Unfair Trade Practice Act, corporations and other companies are considered "person[s]" who can bring claims for violations of the Act. *See* Consumer Opp. Br., Appendix I (citing, *inter alia*, Conn. Gen. Stat. § 42-110a(3); *Elder Bros., Inc. v. Wine Merchs. of Conn., Inc.*, 880 A.2d 138 (Conn. 2005)). By contrast, under Hawaii law, consumers are limited to natural persons, and businesses cannot sue under the Hawaii consumer protection statute. *See id.* (citing, *inter alia*, Haw. Rev. Stat. § 480-1; *Tok Cha Kim v. CB Richard Ellis Haw., Inc.*, 288 F. App'x 312, 314 (9th Cir. 2008)). Similarly, proposed subclass C includes states where businesses likely can bring consumer protection claims (e.g., Georgia, Massachusetts) and states where they likely cannot (e.g., Mississippi, Texas). *See* Consumer Opp. Br., Appendix I. All told, more than 20 states either prohibit or severely restrict businesses from bringing consumer protection claims generally

[2] Defendants understand this to mean the states in which each TPP is headquartered, but *Actiq*, on which the Court's decision relied, placed heavy weight on the states "where doctors made their prescribing decisions" and "where TPPs' beneficiaries transacted for" their medications. *In re Actiq Sales & Mktg. Pracs. Litig.*, 307 F.R.D. 150, 167 (E.D. Pa. 2015). These factors point to the various home states of the TPPs' natural person beneficiaries, making the choice-of-law problem is even more hopelessly complex.

or prohibit anyone from bringing such claims as class actions – and Plaintiffs have made no effort to address these variations in proposing their various subclasses. *See id.* These sorts of differences among state laws, in addition to all of the variations identified in Defendants' Consumer Opposition brief and its appendices, preclude class certification. *See, e.g., Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-cv-1833, 2015 WL 3623005, at *39-40 (E.D. Pa. June 10, 2015).

B. Common Factual Questions Do Not Predominate Over Individualized Ones.

The TPP Plaintiffs also cannot satisfy Rule 23(b)(3)'s predominance requirement because their claims turn on highly individualized questions of fact, particularly with respect to injury, causation/reliance and damages.

1. The TPP Plaintiffs Cannot Prove Injury On A Classwide Basis.

To demonstrate predominance, Plaintiffs must present "evidence that injury to all class members may be proven in one stroke." *Franco v. Conn. Gen. Life Ins. Co.*, 299 F.R.D. 417, 427 (D.N.J. 2014); *see, e.g., Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 190 (3d Cir. 2001) ("[A]scertaining which class members have sustained injury means individual issues predominate over common ones."). The TPP Plaintiffs' classwide theory of injury is based on an assumption that the VCDs at issue were worthless because they contained trace impurities, such that any payment for a VCD necessarily injured each proposed class member. This theory cannot support a finding of predominance for two reasons.

First, as discussed in more detail in Defendants' Consumer Opposition brief, the notion that VCDs had no economic value is contrary to most states' laws and belied by the expert judgment of the FDA; the opinions of patients, TPPs, and health insurers themselves; and common sense. Rather, the evidence could lead a jury to conclude that the VCDs had substantial value to many patients, and by extension, their TPPs. In addition, a jury could easily conclude that VCDs had different values depending on the levels of impurities they contained and the degree of

therapeutic benefit experienced by each patient. If that were the case, a jury would have to make lot-by-lot and patient-by-patient determinations regarding the VCDs' value vis-à-vis their impurity content. These sorts of individualized inquiries cannot be undertaken on a classwide basis.

Second, Plaintiffs lack classwide evidence of injury because some TPPs did not pay for VCDs and others would have had to pay ***more*** money for VCD alternatives. When determining whether a TPP has actually been injured by a manufacturer's alleged wrongdoing, the question is not whether that wrongdoing reduced the medication's value to ***consumers***, but whether the wrongdoing caused an economic harm to the ***TPP***. *See, e.g.*, *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401, 411-12 (11th Cir. 2011) (affirming dismissal of TPP's claim for breach of implied warranty after concluding that the alleged product defect giving rise to the claim—purportedly undisclosed dangerous side effects—did not proximately cause economic harm to the TPP). Thus, the key question in cases like this one is: would the TPPs have paid less for the medication (or nothing at all) if they had known "the truth." *See, e.g.*, *id.* at 409-10 (affirming dismissal of RICO claim where the TPP did not allege it would have "independently determined" that a medication was medically unnecessary had it known the allegedly suppressed information); *Commonwealth v. Ortho-McNeil-Janssen Pharms., Inc.*, 52 A.3d 498, 513 (Pa. Commw. Ct. 2012) (affirming directed verdict for manufacturer after state failed to prove that it would have acted differently—i.e., not paid for the medication—if it had known the "'true' facts about [the medication]"); *see also UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 133-34 (2d Cir. 2010) (reversing certification of TPP class because "excess price theory is not susceptible to generalized proof"). This question cannot be answered on a classwide basis.

For example, in *Actiq*, a putative class of TPPs alleged that Actiq's manufacturer had used unlawful marketing to encourage physicians to write excessive off-label prescriptions. *Actiq*, 307

F.R.D. at 169. The TPPs alleged that this putative misconduct caused them to pay for excessive amounts of Actiq and unjustly enriched the manufacturer. *Id.* While acknowledging that the TPPs could "establish the facts of [the manufacturer's] marketing and sales activities" and whether they were unlawful through classwide evidence, the court concluded that the TPPs could not prove through classwide evidence "that all payments for off-label prescriptions beyond 15% of total quarterly Actiq prescriptions [were] unjust." *Id.* To the contrary, the court concluded, "whether [the] TPPs' payments for Actiq prescriptions resulted in unjust enrichment is a question resolved by examination into the actions not only of [the manufacturer], but also of individual TPPs and prescribing doctors." *Id.* at 171 (citing *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 611 (3d Cir. 2012)). For that reason, the court concluded that common issues did not predominate. *Id.*

The TPP Plaintiffs' class proposal fails for the same reasons. Although the TPP Plaintiffs claim economic injury as a result of paying for allegedly adulterated or misbranded VCDs, "this analysis assumes that [p]laintiffs would not have had to pay for any [anti-hypertensives] at all" had they not purchased the VCDs, and "[t]here is simply no evidence at all to support this highly dubious proposition." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305, 334 (E.D.N.Y. 2014); *see UFCW Local 1776*, 620 F.3d at 135-36 (explaining that TPP would likely have had to pay for alternative medication). In reality, TPPs would almost certainly have paid instead for an alternative medication, and different medications in different cases, depending on each beneficiary's individual medical history. *See* Kosty Rep. ¶¶ 169, 172-73; Ex. 193, Expert Report of Lauren J. Stiroh, Ph.D. ("Stiroh Rep.") ¶¶ 7.vii, 62-64, Jan. 12, 2022. Otherwise, TPPs likely would have borne costs from strokes, heart attacks, cardiovascular disease and other consequences of untreated hypertension. *See* Kosty Rep. ¶ 169.

The TPP Plaintiffs have not presented evidence that any other treatments (let alone all other

treatments) would have cost less than the VCDs at issue in this litigation. Rather, that question would turn on each TPP's formularies, reimbursement schedules, and even the demographics and medical histories of each TPP's beneficiaries. [redacted]. Stiroh Rep. ¶ 64. Other TPPs may have paid less or the same, requiring highly individualized inquiries. For this reason, too, the TPP Plaintiffs cannot demonstrate predominance.

2. The TPP Plaintiffs Cannot Show That They Uniformly Relied On The Manufacturer Defendants' Statements.

Plaintiffs' class proposal also fails to satisfy Rule 23(b)(3)'s predominance requirement because of the need for individualized reliance inquiries to address their claims for fraud, breach of express warranty and (under many states' laws) consumer protection violations. *See UFCW Local 1776*, 620 F.3d at 134 (plaintiffs could not show uniform "reliance by the TPPs"); *see also Actiq*, 307 F.R.D. at 171 (denying class certification after concluding that the TPPs' unjust enrichment claims required individualized determinations of causation); *Vista Healthplan*, 2015 WL 3623005, at *34 (similar); Consumer Opp. Br., Appendices F-K, M-N.

There are at least two different models by which a TPP can determine which medications to cover. Some TPPs run their own P&T Committees to make formulary decisions. The majority, however, simply adopt formularies prewritten by a PBM. *See* Kosty Rep. ¶ 68 (73% of employers adopt a PBM's formulary). Plaintiffs' expert Dr. Panagos explains that P&T Committees "typically" are part of a PBM, and that only in "some cases" will a TPP have its own "in-house" P&T Committee. *See* Panagos Rep. ¶ 22 & n.2. P&T Committees consider a host of factors in deciding what medications to cover, and these factors vary from Committee to Committee, raising daunting individual reliance issues. In developing their formularies, P&T Committees may rely on medical literature, clinical evidence, economic data, provider recommendations, package inserts,

product labels, trial data and patient experiences. Kosty Rep. ¶ 199. Moreover, P&T Committees rarely consider multi-source, generic medications on a manufacturer-by-manufacturer basis; instead, they assess whether a generic version of a drug, irrespective of the manufacturer, should be included on a formulary. *Id.* ¶ 198. It is therefore illogical to argue that P&T Committees based their decisions to include VCDs on formularies on six specific manufacturers' labels, FDA submissions or Orange Book listings.

In addition, TPPs that adopted PBM-written formularies did not rely on anything, much less on Defendants' alleged misrepresentations. For example, named plaintiff MADA did not even ***see*** the formulary that applies to its plans, much less choose the medications listed therein. Brown Dep. 96:4-19. Plaintiffs contend that the PBMs are "agents" for "TPPs and their . . . [P&T] Committees," TPP Br. at 4, suggesting that the PBMs' reliance can somehow be imputed to the TPPs themselves. But even if that were so, it would merely underscore the individualized nature of the issue. After all, in order to determine reliance for these TPPs, a trier of fact would have to determine which outside PBM each putative class member relied upon, and then evaluate all of the factors that the outside PBM considered in drafting a formulary.

In an effort to gloss over these individualized questions, the TPP Plaintiffs conflate a listing in the Orange Book with a guarantee that any generic drug listed therein is "pharmaceutically equivalent, therapeutically equivalent, and bioequivalent" to its Reference Listed Drug and that any listed generic drug "satisfie[s] all compendia, quality, purity and other requirements; complied with all cGMPs; and were safe for consumption." TPP Br. at 5.[3] Dr. Panagos goes so far as to claim that an Orange Book rating "represents a manufacturer's warranty to TPPs and P&T

[3] The TPP Plaintiffs incorrectly imply that compliance with cGMP is part and parcel of "bioequivalence." TPP Br. at 5. The Orange Book's definition of "bioequivalence" states nothing about cGMP, purity or "other requirements."

Committees for" formulary placement. Panagos Rep. ¶ 47. But despite reviewing "countless minutes from P&T [C]ommittees," Dr. Panagos could not provide a single example of reliance by a P&T Committee on the Orange Book. Ex. 51, Dep. of Kali Panagos 41:11-24, 120:2-121:10, Jan. 21, 2022. The Orange Book never mentions the word "warranty" and disclaims any connection between compliance with regulations and inclusion of a product in the publication.[4] And Mr. Kosty confirms that P&T Committees "do not consider the Orange Book to represent any sort of warranty." Kosty Rep. ¶ 196.[5]

For all of these reasons, reliance cannot be determined on a classwide basis—and would have to be proven by each TPP separately—further precluding class certification.

3. The TPP Plaintiffs Do Not Have A Viable Classwide Theory Of Damages.

A party seeking to prove damages on a classwide basis must provide a model to "establish[] that damages are capable of measurement" classwide, lest individualized damages issues "overwhelm questions common to the class." *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013); *see also, e.g., Johnson v. GEICO Cas. Co.*, 310 F.R.D. 246, 255 (D. Del. 2015) (denying certification where "[c]ommon liability issues do not predominate over individualized damages issues"), *aff'd*, 672 F. App'x 150 (3d Cir. 2016); *Harding v. Jacoby & Meyers, LLP*, No. 14-5419, 2017 WL 4922010, at *7 (D.N.J. Oct. 30, 2017) ("[P]laintiff seeking class certification must present evidence of a reliable methodology for calculating damages on a class-wide basis.")

[4] FDA, Orange Book Introduction § 1.6 (42d ed. 2022) (enforcement of the federal Food, Drug and Cosmetic Act ("FDCA") is "independent of the inclusion of a product in the Orange Book").

[5] Dr. Ron Najafi advances the related theory that a generic drug must be the "same[]" as the brand-name Reference Listed drug. ECF 1748-3, Expert Decl. of Ron Najafi, Ph.D. ¶ 18, Nov. 4, 2021. But as he acknowledged at his deposition, that requirement addresses ingredients, strength and mode of administration; it does ***not*** require the same impurity profile. *See* Ex. 52, Dep. of Ron Najafi 18:24-21:4, Feb. 3, 2022. There is also evidence that certain lots of the Reference Listed drug contained the NDMA impurity, further undermining Dr. Najafi's theory. *Id.* 143:12-147:20.

(citation omitted). Importantly, a classwide damages model is invalid if it "identifies damages that are not the result of the wrong." *Comcast*, 569 U.S. at 37.[6]

Plaintiffs propose to address these requirements through the testimony of their expert Dr. Conti. But Dr. Conti's grossly oversimplified model cannot support class certification for several reasons.

First, as discussed above, the TPP Plaintiffs' model for proving both injury and damages depends on the erroneous contention that all VCDs were categorically "worthless." *See generally supra* § I(B); Consumer Opp. Br. § I(B)(4). But the trier of fact would have to individually evaluate the alternative therapies that each TPP would have paid for if the VCDs not been available on the market, and whether those therapies would have been more or less expensive. *See* Kosty Rep. ¶ 169; Stiroh Rep., Section IV. This is a paradigmatic individualized inquiry that would require analysis of the formulary applicable to each plan, the benefit structure of each plan, the available alternative therapies under the applicable formulary and the actual drug that would have been selected by each consumer and his or her physician.

Second, Dr. Conti's model cannot calculate classwide damages because it is based on an erroneous assumption that the price TPPs pay at the time the consumer fills a prescription fully represents the cost to the TPP. It does not, and Dr. Conti admits as much.

As discussed above, the amount of money that the TPP Plaintiffs actually paid toward

[6] Plaintiffs contend that "'individual damages allocation issues are insufficient to defeat class certification.'" TPP Br. at 18 (quoting *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 233 (E.D. Pa. 2012)). But *Flonase* acknowledged that "[c]omplex and individual questions of damages . . . weigh against finding predominance." 284 F.R.D. at 232 (citation omitted). That was not the case in *Flonase* because the plaintiff had proposed a "reasonable estimate of the class-wide damages." *Id.* at 233 (citation omitted). Here, by contrast, the sole damages model the TPP Plaintiffs put forward is too flawed to measure damages either on an aggregate or individualized basis. In any event, *Flonase* predates *Comcast*, which clarified the need for a classwide damages model.

VCDs was affected by a host of pre- and post-sale adjustments. For example, TPPs may have received money back from their PBMs pursuant to a performance guarantee covering VCDs, refunds following claim reversals, or retiree drug subsidies. In addition, pharmacies and PBMs typically charge TPPs a flat dispensing fee for each prescription filled, which "differ[s] from" "pharmacy to pharmacy." Kosty Rep. ¶ 40(d)(ii). Moreover, a large number of TPP class members—accounting for 42% of the damages estimated—provide government-funded insurance pursuant to Medicare Part D. *See id.* ¶ 176. Those TPPs' costs would have been subsidized and/or reimbursed in substantial part by the federal government, in varying amounts. *Id.* ¶¶ 176-177. PBMs may also charge government-funded insurance plans direct and indirect remuneration fees, which further complicate efforts to quantify damages. As Mr. Kosty explained, these fees "are not allocated on a drug-by-drug basis"; thus, the effect of valsartan prescriptions on those fees would be nearly impossible to isolate. *Id.* ¶ 40(d)(iv).

Dr. Conti's model does not account for any of this, as she forthrightly admits. Conti Decl. ¶ 56 n.52 [redacted]. By including costs that TPPs did not actually themselves pay, Dr. Conti has produced a damages model that "identifies damages that are not the result of the wrong." *Comcast*, 569 U.S. at 37; *In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 575 (E.D. Tenn. 2014) ("[T]he incongruity between End Payors' description of class membership and the entities included in its impact and damages model might [also] defeat this proposed class."); *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 149 (E.D. Pa. 2015) (decertifying TPP class because it was "unclear . . . that if PBMs [were] excluded[—to avoid ascertainability issues—] 'damages [would be] susceptible to measurement across the entire class'").

Awarding the TPP Plaintiffs the full amounts paid at the "point of sale" would result in a

massive windfall, particularly with respect to TPPs that provide Medicare Part D/Advantage plans and state MMC plans. Nor is there any classwide fix for this problem. Given the variation among TPPs and the price adjustments each one uniquely received during the class period, attempting to calculate the net price paid by the TPPs for VCDs at issue in this litigation would require an individualized analysis into each TPP class member's net VCD costs, such that classwide questions could not predominate. For this reason, too, the TPP Plaintiffs' motion should be denied.

II. PLAINTIFFS' CLASS PROPOSAL FAILS THE SUPERIORITY/ MANAGEABILITY REQUIREMENT OF RULE 23(B)(3).

The "polestar of Rule 23(b)(3)" is "how a trial of this controversy, if tried as a class action, could be efficiently and fairly managed." *In re LifeUSA Hldg. Inc.*, 242 F.3d 136, 148 (3d Cir. 2001); *see also* Fed. R. Civ. P. 23(b)(3)(D). Thus, courts routinely deny class certification where the proposed class trial would involve an enormous number of individual determinations and "countless minitrials." *See, e.g., Johnston v. HBO Film Mgmt., Inc.*, 265 F.3d 178, 194 (3d Cir. 2001). Plaintiffs apparently propose to try this case together with their proposed consumer class action. *See* TPP Br. at 22 ("Plaintiffs' Economic Loss Trial Management Plan and Structure demonstrates that both Consumer and TPP economic loss class claims can be tried as a practical matter."). As Defendants' Consumer Opposition brief explains, any such trial, which would include a whopping ***114 subclasses***, thousands upon thousands of pages of jury instructions, and a book-length "questionnaire" in place of a verdict form, not to mention three phases and two independent factfinders, is almost impossible to fathom. *See* Consumer Opp. Br. § II; *see also, e.g., Lilly v. Ford Motor Co.*, No. 00 C 7372, 2002 WL 507126, at *3 (N.D. Ill. Apr. 3, 2002) (manageability problems cannot "be obviated by the use of subclasses and special verdict forms").

To the extent the TPP Plaintiffs alternatively propose a single, separate, TPP-specific trial, it would be nearly as unmanageable. Plaintiffs have not even explained how the TPP claims could

be manageably tried. That alone cuts strongly against a finding of manageability. *See* Fed. R. Civ. P. 23 advisory committee's notes to 2003 amendment ("An increasing number of courts require a party requesting class certification to present a 'trial plan' that describes the issues likely to be presented at trial and tests whether they are susceptible of class-wide proof.") (quoted with approval in *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 319 (3d Cir. 2008), *as amended* (Jan. 16, 2009)); *Vega v. T-Mobile USA, Inc.*, 564 F.3d 1256, 1279 n.20 (11th Cir. 2009) ("We . . . recommend that district courts make it a usual practice to direct plaintiffs to present feasible trial plans, which should include proposed jury instructions . . . ."). Moreover, any proposal Plaintiffs might put forward for a TPP trial would be hopelessly unmanageable. While a TPP-specific trial would be somewhat less chaotic than a joint trial of TPP and individual consumer claims, it would still include 21 subclasses and would be almost as complex. The jury would still have to apply the laws of 52 different jurisdictions. *See Powers v. Lycoming Engines*, 328 F. App'x 121, 127 (3d Cir. 2009) ("Attempting to apply the law of a multiplicity of jurisdictions can present problems of manageability for class certification under Rule 23(b)(3)."); *Skelaxin*, 299 F.R.D. at 588 ("Applying the law of forty-nine states likely renders this class simply unmanageable."). The model jury instructions for the claims brought by the TPPs total approximately 1,200 pages and contain more legal standards than any fact-finder could possibly be asked to absorb and apply.

Individual trials would avoid these complexities and provide an obviously superior alternative, especially because "one of the main reasons for finding superiority in a class action—the existence of a negative value suit—is absent in this case." *Arch v. Am. Tobacco Co.*, 175 F.R.D. 469, 496 (E.D. Pa. 1997); *Reap v. Cont'l Cas. Co.*, 199 F.R.D. 536, 550 (D.N.J. 2001) ("a class action is not warranted when proposed class members have both the incentive and the ability to protect their own interests"). There has been no suggestion in this case that the costs of individually

litigating the TPP Plaintiffs' claims would render their claims valueless. Unlike the individual consumer class members, each TPP class member almost certainly paid for hundreds or thousands of VCD prescriptions during the class period. *See Actiq*, 307 F.R.D. at 172 (denying class certification in part because "TPPs are sophisticated institutional entities with an interest in controlling litigation when relatively large amounts of money are at stake"). Thus, each class member's individual claim is sufficiently valuable to try alone. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 617 (1997) ("'The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action . . . . A class action solves this problem by aggregating the relatively paltry potential recoveries into something worth someone's (usually an attorney's) labor.'"). Plaintiffs' suggestion that even if individual trials are feasible, a single class trial "is superior to the alternative of thousands of individual actions," TPP Br. at 21, is backwards. "[I]t is not a waste of judicial resources to conduct more than one trial, before more than six jurors," when "aggregate stakes [are] in the tens or hundreds of millions of dollars." *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1300 (7th Cir. 1995).

In sum, "[t]he superiority requirement 'asks the court to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication.'" *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 533-34 (3d Cir. 2004) (citation omitted). Here, that balance weighs overwhelmingly against certifying the proposed TPP class. For this reason, too, the TPP Plaintiffs' motion should be denied.

III. THE TPP PLAINTIFFS ARE NOT TYPICAL OR ADEQUATE CLASS REPRESENTATIVES.

Typicality requires that "a class representative . . . be part of the class and 'possess the same interest and suffer the same injury' as the class members." *Wal-Mart Stores, Inc. v. Dukes*,

564 U.S. 338, 348-49 (2011) (citations omitted). The typicality inquiry "properly focuses on the similarity of the legal theory and legal claims; the similarity of the individual circumstances on which those theories and claims are based; and the extent to which the proposed representative may face significant unique or atypical defenses to her claims." *In re Schering Plough Corp. ERISA Litig.*, 589 F.3d 585, 597-98 (3d Cir. 2009). "The adequacy inquiry under Rule 23(a)(4) serves to uncover conflicts of interest between named parties and the class they seek to represent." *Amchem*, 521 U.S. at 625. Plaintiffs fail both of these requirements.

A. Both Named Plaintiffs Are Inadequate Class Representatives Because They Lack Standing.

As a threshold matter, neither named Plaintiff is an adequate class representative because they both lack Article III standing, and are therefore "not entitled to represent the . . . class." *McNair v. Synapse Grp., Inc.*, 672 F.3d 213, 222-23 (3d Cir. 2012). To meet the "irreducible constitutional minimum" of standing, the "plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016), *as revised* (May 24, 2016). An injury must be "concrete," i.e., it must be "de facto," "real," and "actually exist; "a bare procedural violation" will not do. *Id.* at 339-41; *see also, e.g., TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2205 (2021) ("Only those plaintiffs who have been concretely harmed by a defendant's statutory violation may sue"). The TPP plaintiffs cannot show injury in fact because they have not provided any evidence that they actually lost money. Rather, their claims are based solely on the argument that a provision of the FDCA—21 U.S.C. § 331—prohibits the sale of "adulterated" or "misbranded" products, rendering any non-compliant product worthless. Dr. Conti attempts to manufacture an injury by opining that the at-issue VCDs provided "no economic value," Conti Decl. ¶ 42, but, as explained above, and in Defendants' forthcoming

Daubert motion, her opinions are not based on a reliable methodology and fly in the face of common sense. For this reason, too, Plaintiffs' class proposal does not satisfy Rule 23.

B. The Named Plaintiffs Are Atypical And Inadequate For Other Reasons Too.

1. MSPRC Is Not An Adequate Or Typical Class Representative.

MSPRC, which is not a TPP and has never paid for VCDs, is an atypical and inadequate class representative for several additional reasons.[7]

First, MSPRC's status as an assignee, rather than a true TPP, raises unique issues that will divert the focus of the litigation. Class certification is inappropriate where, as here, a proposed class representative "is subject to unique defenses which threaten to become the focus of the litigation." *Gary Plastic Packaging Corp. v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 903 F.2d 176, 180 (2d Cir. 1990), *abrogated on other grounds by Microsoft v. Baker*, 137 S. Ct. 1702 (2017). Such defenses make certification inappropriate because they reflect the "danger that absent class members will suffer if their representative is preoccupied with defenses unique to it." *Id.*; *accord Randall v. Rolls-Royce Corp.*, 637 F.3d 818, 821 (7th Cir. 2011) (named plaintiff can be found to be atypical, precluding class certification, where that plaintiff is subject to "a possibly complete defense to his claim that may not apply to claims of the other class members").

Determining the validity and scope of MSPRC's assignments, and MSPRC's standing to pursue the purportedly assigned claims, will require fact-intensive inquiries that are irrelevant to absent class members. For example, the assignment from SummaCare, Ex. 41, MSP 0001152-72, which is governed by Ohio law, is unenforceable as champertous, *see Rancman v. Interim*

[7] Plaintiffs claim that "MSPRC's similar affiliate . . . was recently certified as a class representative" in a Florida state court case, TPP Br. at 14, but that case is currently on appeal. Notably, the trial court previously certified a similar class and that ruling was reversed. *See IDS Prop. & Cas. Ins. Co. v. MSPA Claims 1, LLC*, 263 So. 3d 122 (Fla. Dist. Ct. App. 2018).

Settlement Funding Corp., 789 N.E.2d 217, 219 (Ohio 2003) (agreement was void as champerty and maintenance where a nonparty undertook to further another's interest in a lawsuit in exchange for a share of any litigation proceeds); *Hiles v. NovaStar Mortg., Inc.*, No. 12-cv-392, 2012 WL 4813775 (S.D. Ohio Oct. 10, 2012) (plaintiff lacked standing as assignee where assignment was void as champertous under Ohio law); *see also MSP Recovery Claims, Series LLC v. Grange Ins. Co.*, No. 19cv00219, 2019 WL 6770729, at *11 (N.D. Ohio Dec. 12, 2019) (vesting of future assignments under the SummaCare agreement was prohibited under Ohio law). Thus, at least some of MSPRC's claims will be subject to unique factual inquiries and defenses.

Second, MSPRC is neither an adequate nor typical class representative because it is in the business of filing lawsuits, in contrast to the majority of class members, whose business is providing healthcare coverage. *See* Lopez Dep. 168:15-170:16; *MAO-MSO Recovery II, LLC v. State Farm Mut. Auto Ins. Co.*, No. 17-cv-1537, 2018 WL 6634324, at *5 (C.D. Ill. Dec. 19, 2018) (noting "significant" question as to whether a plaintiff that "exist[s] solely to collect reimbursements from" insurers could adequately represent organizations that actually "administer Medicare Advantage Plans in a traditional sense"). Moreover, MSPRC's lawsuits generally target the very industry it now wants to represent. *Cf. Glictronix Corp. v. AT&T Co.*, 603 F. Supp. 552, 586 (D.N.J. 1984) (named plaintiff "cannot adequately represent its rivals"). In fact, MSPRC is so committed to suing insurance companies that "multiple district courts have already commented on what they perceive as [its] rush to file litigation in the hope that discovery will show whether an actual case or controversy exists." *MAO-MSO Recovery II, LLC v. State Farm Mut. Auto. Ins. Co.*, 994 F.3d 869, 878 (7th Cir. 2021) (collecting cases and affirming grant of summary judgment for defendant insurers in action brought by MSPRC and related entities).

Third, all of the claims assigned to MSPRC arise from Medicare Advantage plans that are partially subsidized by Medicare. Such plans are funded in whole or in part by the government (e.g., Medicare Part D plans and Medicaid Managed Care Organizations) and are not typical of other TPPs because the amount of risk they bear for a particular prescription drug claim (if any) varies not just on whether the plan is fully- or self-insured, but on the form and amount of government subsidies the plans receive. Notably, the TPP Plaintiffs' proposed class definitions exclude "[a]ll federal and state governmental entities" except for municipal self-funded prescription drug plans. Mot. for Class Certification Ex. B (ECF 1747-2) at 4. Separating the excluded and non-excluded (if any) portions of MSPRC's claims presents unique and individualized challenges not typical of other putative TPP class members.

2. MADA Is Not An Adequate Or Typical Class Representative.

MADA is also an atypical and inadequate class representative because it has little actual knowledge of the claims being asserted in this litigation. *See Kirkpatrick v. J.C. Bradford & Co.*, 827 F.2d 718, 727 (11th Cir. 1987) ("[D]istrict courts . . . have properly denied class certification where the class representatives had so little knowledge of and involvement in the class action that they would be unable or unwilling to protect the interests of the class against the possibly competing interests of the attorneys."). At his deposition, MADA's corporate representative was generally uninformed about how much was paid by MADA for VCDs or the process by which MADA's liability for VCDs is calculated. *See, e.g.*, Brown Dep. 28:7-25, 115:18-116:1. Instead, the MADA representative generally referred everything to "Anthem," a third-party administrator. *Id.* 28:7-25, 44:24-45:22. MADA's corporate representative also testified that MADA itself never reviewed any representations from any defendant in this case about valsartan, and instead relied upon a formulary provided to pharmacies by Anthem, which MADA did not review. *Id.* 71:13-25, 96:11-19, 98:6-17. While it is not uncommon for a TPP to adopt a formulary from a PBM,

MADA's ignorance raises serious questions about its ability to adequately supervise the course of this litigation. "[I]f [a] plaintiff 'displays . . . a lack of knowledge or understanding concerning what the suit is about, then the court may conclude that [the adequacy requirement] is not satisfied.'" *Shiring v. Tier Techs., Inc.*, 244 F.R.D. 307, 315 (E.D. Va. 2007) (quoting 7A Charles Allen Wright et al., *Federal Practice and Procedure* § 1766 (2007)).

Anthem was likewise uninformed about any of the specifics of MADA's prescription drug plan or any of the factors (e.g., rebates, dispensing fees, subsidies, claims recovery efforts, penalties for failure to meet guarantees, etc.) that have been identified to affect the ultimate cost to the TPP. Cobb Dep. 44:20-47:14. Instead, Anthem referred a number of questions to "the PBM," which at the time was Express Scripts. *Id.* 24:1-5, 58:4-13, 62:4-63:12, 74:19-76:17, 84:6-14, 85:17-87:1, 103:9-23, 110:4-113:5. In short, MADA is ultimately reliant on a separate company for critical information about this case, further reflecting the complicated relationships and structure of TPPs and confirming that MADA is not a proper class representative. *See, e.g., In re Kosmos Energy Ltd. Sec. Litig.*, 299 F.R.D. 133, 145 (N.D. Tex. 2014) (applying "rigorous adequacy review" to institutional plaintiff).

IV. THE TPPS HAVE NOT SHOWN THAT THE CLASS IS ASCERTAINABLE

In addition to all of the explicit requirements of Rule 23, a plaintiff seeking class certification must also demonstrate ascertainability: (1) that the class is "defined with reference to objective criteria"; and (2) that "there is 'a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.'" *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015) (quoting *Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d 349, 355 (3d Cir. 2013)). As with the explicit Rule 23 requirements, the requisite showing is subject to a rigorous analysis: "a party cannot merely provide assurances . . . that it will later meet Rule 23's requirements[,] nor may a party 'merely propose a method of ascertaining a class without any

evidentiary support that the method will be successful.'" *Byrd*, 784 F.3d at 164 (quoting *Carrera v. Bayer Corp.*, 727 F.3d 300, 306 (3d Cir. 2013)). Here, the TPP Plaintiffs have failed to demonstrate that their proposed class is ascertainable because the class definition is administratively infeasible and impermissibly vague.

A. Many TPPs Are Not Identifiable In An Administratively Feasible Way Using The Method The TPP Plaintiffs Propose.

The TPP Plaintiffs' contention that they can use industry data to ascertain membership of the TPP class, TPP Br. at 15-16, ignores the limitations of those data. "Administrative feasibility means that identifying class members is a manageable process that does not require much, if any, individual factual inquiry." *Carrera*, 727 F.3d at 307-08 (citation omitted). The TPP Plaintiffs contend that they "need not . . . demonstrate that a single record, or set of records, conclusively establishes class membership" at this stage, TPP Br. at 15 (citation omitted), but the fact remains that "[i]f class members are impossible to identify without extensive and individualized fact-finding or 'mini trials,' then a class action is inappropriate," *Marcus*, 687 F.3d at 593.

Notably, courts routinely deny class certification where TPPs provide only vague assurances that a class is ascertainable despite a complex class definition. *See, e.g.*, *Vista Healthplan*, 2015 WL 3623005, at *10-11 (denying class certification and noting that "plans to create [an ascertainability] methodology at a later date do not satisfy the rigorous analysis insisted upon by the Third Circuit"); *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 705 (E.D. Pa. 2020) (denying class certification motion premised on opinion of Plaintiffs' expert here; "While Craft's report constitutes admissible evidence, the [c]ourt does not find that her report establishes . . . that [End-Payor Plaintiffs ("EPPs")] have an administratively feasible methodology for identifying class members."); *In re Niaspan Antitrust Litig.*, MDL No. 2460, 2021 WL 3629076, at *10 (E.D. Pa. Aug. 17, 2021) ("*Niaspan II*") (denying renewed motion for class certification;

"The [c]ourt concludes that EPPs have not presented an administratively feasible mechanism to distinguish between class members and mere intermediaries such as fully insured plans."); *Wellbutrin*, 308 F.R.D. at 149-51 (decertifying class after concluding that "[t]he [Indirect Purchaser Plaintiff Class]'s evidence on ascertainability barely goes further than repeated assurances that showing ascertainability in pharmaceutical cases is not difficult and that there are extensive purchase records in the pharmaceutical industry that could be used to ascertain whether individual consumers and PBMs are members of the class").

Here, the TPP Plaintiffs fail to offer an administratively feasible method to identify entities that should be in the class (because they bore financial risk) versus entities that should not be in the class (because they are fully-insured or intermediaries and therefore did not bear financial risk).[8] To identify TPP class members and exclude fully-insured plans and intermediaries, the TPP Plaintiffs and their expert, Laura Craft, propose to use a combination of (1) pharmacy-provided data and (2) PBM-provided data. *See* Craft Decl. ¶¶ 17, 45, 63-68; TPP Br. at 15. But the TPP Plaintiffs fail to explain how these data can be combined or used; they merely assure the Court that "data exist and can be used to identify which . . . TPPs paid for which VCDs . . . in an objective, administratively feasible manner." *See, e.g.*, TPP Br. at 15-16.

In reality, the evidence shows that the TPP Plaintiffs' proposal is not administratively feasible for at least two reasons. First, pharmacy claims data do not identify the final end payors that are ultimately "at risk" for the claims (i.e., the TPPs). *See* Craft Dep. 265:8-269:21 (acknowledging that the National Council for Prescription Drug Programs data that pharmacies

[8] Roughly 88% of employers obtain "fully insured" coverage from insurance companies—and those TPPs must be weeded out to avoid an over-inclusive class. *See Niaspan II*, 2021 WL 3629076, at *7 (any methodology for ascertaining end-payor class must distinguish self-funded TPPs using an intermediary's services from fully insured plan sponsors in an administratively feasible way).

use to transmit claims to PBMs are merely alphanumeric codes—not names, descriptions, or identifiers—and are not designed to identify TPPs or relationships that a plan sponsor may have with a TPA/ASO); *Niaspan II*, 2021 WL 3629076, at *8 (noting Ms. Craft's previous admission of the same). And second, while PBM data sometimes identify the "at risk" payor, they often do not, particularly when the TPP has not contracted directly with the PBM. *See* Craft Dep. 149:8-13 (admitting that PBM data do not always identify the ultimate "at risk" payor). Indeed, 51% of self-funded employers who provide health coverage to employees contract with at least one TPA or ASO intermediary instead of dealing directly with a PBM, adding one more link to the chain and further complicating the task of identifying the at-risk payor. Kosty Rep. ¶ 60. For all of these reasons, the data that the TPP Plaintiffs identify do not furnish an administratively feasible and reliable way of ascertaining the proposed TPP class.[9]

B. The TPP Class Definition Is Too Vague To Ascertain Its Members

The TPP Plaintiffs also cannot establish ascertainability because they do not define what a "Third-Party Payor" actually is. An "unworkably vague" class definition cannot be certified. *Martinez v. Equifax Inc.*, No. CV 15-2100 (SRC), 2016 WL 226639, at *3 (D.N.J. Jan. 19, 2016). Throughout their complaint and brief, the TPP Plaintiffs refer to "Third-Party Payors" as if it were a defined term. But the TPP Plaintiffs do not define the term in the operative complaint or in their motion for class certification. While the TPP Plaintiffs' brief describes TPPs as "health care benefit

[9] The TPP Plaintiffs may attempt to distinguish *Niaspan II* on the ground that other courts outside the Third Circuit have accepted her methodologies. TPP Br. at 17 (making vague reference to "[o]ther federal court[]" decisions). But those courts were not bound by the Third Circuit's well-established parameters for ascertainability, in particular, the requirement that ascertaining a class must be administratively feasible. *Niaspan II*, 2021 WL 3629076, at *9-10. In addition, those cases simply accepted Ms. Craft's bald assertions that she could obtain and manipulate the data necessary to ascertain class members, instead of engaging in the necessary rigorous fact-finding to ensure that the requirements of Rule 23 are actually met.

providers, such as an employer's insurance company or a health and welfare plan," TPP Br. at 2, this description is inconsistent with how the prescription drug industry uses the term "third-party payor," *see* Kosty Rep. ¶ 56. It also contradicts named TPP Plaintiff MSPRC's own understanding of the term. MSPRC's representative testified that its downstream entity assignors, such as physician offices and other healthcare providers, *see* ECF 650 at 1 & Ex. A, could fall within the TPP class, Lopez Dep. 40:13-41:21, even though these entities are neither insurance companies nor health and welfare plans. Contrasting MSPRC's interpretation with the TPP Plaintiffs' description of "Third-Party Payors" as "benefit providers," *see* TPP Br. at 2, it is clear that the term does not have a sufficiently objective meaning to allow the Court to ascertain the class.

CONCLUSION

For the foregoing reasons, the TPP Plaintiffs' motion should be denied.

Dated: April 12, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 12, 2022, I electronically filed the foregoing Defendants' Opposition to Plaintiffs' Motion for Class Certification of Third-Party Payor Claims with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants.

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